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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/814,705	03/30/2004	J. Richard Gyory	ALZA-0377/ALZ5016USANP	7214

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WOODCOCK WASHBURN LLP
CIRA CENTRE, 12TH FLOOR
2929 ARCH STREET
PHILADELPHIA, PA 19104-2891

EXAMINER

GILBERT, ANDREW M

ART UNIT	PAPER NUMBER
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3767

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/08/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/814,705

Applicant(s)

GYORY, J. RICHARD

Examiner

Andrew M. Gilbert

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 October 2006.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 9/21/2006 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/19/2006 has been entered.

Acknowledgments

2. This office action is in response to the reply filed on 10/19/2006. In the reply, the applicant amended claims 1; amended the specification; and submitted replacement drawing for Figure 5.
3. The amendment to claim 1 obviates the 35 U.S.C. 112 first paragraph rejection as failing to comply with the written description requirement.
4. The amendment to the specification obviates the objection to the specification under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. The cancellation of new subject matter obviates the objection.
5. The amendment of Figure 5 does not obviate the objection to Figure 5 as new matter. See below.

Specification

6. The amendment filed 10/19/2006 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no

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amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: The submission of newly added Figure 5 showing the device depicted in Figure 4, as well as a second set of the elements depicted in Figure 4, including a first reservoir containing an active agent formulation, because nowhere in the specification as originally filed, including original claim 1, *does the applicant sufficiently describe their invention so as to produce Figure 5*. The introduction of Figure 5 introduces new matter because via Figure 5 the applicant can now seek to claim, for instance, that the flexible region (105) is shaped in a U-shape or the physical contact relationship between the electrode and the active agent reservoir that was not sufficiently described in their originally filed specification and drawings.

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

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8. Claims 1-4, 6 are rejected under 35 U.S.C. 102(b) as being anticipated by Tapper (5224927). Tapper discloses an electrotransport device (10) having a first (16a) electrode, the first electrode in communication with a first reservoir (18a) adapted to receive an active agent formulation that is a therapeutic agent (col 8, Ins 12-16; col 11, Ins 66-67), a power source (32) in communication with electronic circuitry (15) in communication with first electrodes (Fig 1-3, col 7, Ins 47-col 8, Ins 51), a non-conductive reservoir housing (14) having an internal cavity (Fig 3) containing said first electrode (16a) and first reservoir (18a) and the reservoir housing having an electrically conductive element (16a, 21a) integrally molded within the non-conductive housing and that is substantially planar (Fig 3, 16a), flexible (16a, 21a, Fig 3, col 7, Ins 47-col 8, Ins 51), and that has a first end in communication with the first reservoir (16a) and a second end that is disposed on the outside of the reservoir housing (21a) and extending therefrom to be operatively connected to the power source through the electronic circuitry (21a, col 7, Ins 47-col 8, Ins 51).

9. Claims 1-6 rejected under 35 U.S.C. 102(b) as being anticipated by Flower (5857994). Flower discloses an electrotransport device (Fig 1) having a first (8) electrode, the first electrode in communication with a first reservoir (14) adapted to receive an active agent formulation that is a therapeutic agent (12; Summary), a power source (22) in communication with electronic circuitry (24) in communication with first electrodes (8), a non-conductive reservoir housing (4) having an internal cavity (Fig 1-2) containing said first electrode (8) and first reservoir (14) and the reservoir housing

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having an electrically conductive element (8, 26; Fig 1-2) integrally molded within the non-conductive housing and that is substantially planar (26, Fig 1), flexible (26, Fig 1), with a conductive coating (26; Fig 1, col 4, lns 28-31) and that has a first end in communication with the first reservoir (Fig 1-2) and a second end that is disposed on the outside of the reservoir housing (Fig 1-2) and extending therefrom to be operatively connected to the power source through the electronic circuitry (Figs 1-5; col 4, lns 15-col 5, lns 50).

10. Claims 1-11, 15-16 are rejected under 35 U.S.C. 102(e) as being anticipated by Kuribayashi et al (6915159). Kuribayashi et al discloses an electrotransport device (Figs 1-12) having a first (2) electrode, the first electrode in communication with a first reservoir (20, 12) adapted to receive an active agent formulation that is a therapeutic agent (20, col 9, lns 42-col 10, lns 46), a power source (1d, Fig 8) in communication with electronic circuitry (18, Fig 8) in communication with first electrodes (2), a non-conductive reservoir housing (1) having an internal cavity (Fig 1, 6) containing said first electrode (2) and first reservoir (12, 20) and the reservoir housing having an electrically conductive element (2) integrally molded within the non-conductive housing and that is substantially planar (2, Fig 1, 6), flexible (2, Fig 1,6), with a conductive coating (col 7, lns 1-5, 39-47) and that has a first end in communication with the first reservoir (Fig 1, 6) and a second end that is disposed on the outside of the reservoir housing (Fig 1, 6, 2, 14, 15, 17) and extending therefrom to be operatively connected to the power source through the electronic circuitry (Fig 1, 6, 8-11).

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. Claims 12-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kuribayashi et al. Kuribayashi et al discloses the invention substantially as claimed except for expressly disclosing wherein the active agent formulation includes a therapeutic agent being the specific agents disclosed in the applicant's claims 12-14. At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to have the therapeutic agent being the specific agents disclosed in the applicant's claims 12-14 because the Applicant has not disclosed that having the therapeutic agent being the specific agents disclosed in the applicant's claims 12-14 provides an advantage, is used for a particular purpose, or solves a stated problem. Furthermore, one of ordinary skill in the art would have expected the Applicants invention to perform equally well with therapeutic agents of Kuribayashi et al because the Applicant has not given any criticality for the therapeutic agents being the specifically claimed agents. Therefore, it would have been an obvious matter of design choice to modify Linkwitz et al to obtain the invention as specified in claims 12-14.

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Response to Arguments

13. Applicant's arguments with respect to claims 1-16 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion


The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Jain et al (8829968); Flower (5830175); Jones (4911688); Jacobsen et al (4141359); Anderson et al (6653014).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andrew M. Gilbert whose telephone number is (571) 272-7216. The examiner can normally be reached on 8:30 am to 5:00 pm Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571)272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Andrew Gilbert

KEVIN C. SIRMONS
SUPERVISORY PATENT EXAMINER

